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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/148,012	09/04/1998	MONTY KRIEGER	MIT7150CIP(2	2616

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Patrea L Pabst  
HOLLAND & KNIGHT LLP  
One Atlantic Center  
1201 West Peachtree Street Suite 2000  
Atlanta, GA 30309

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

25

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/148,012

Applicant(s)

KRIEGER, MONTY

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10,12,15,16 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,12,15,16 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***1. Formal Matters***

A. Amendment E, filed 11/20/02, has been entered into the record. Claim 1-22 were pending. Applicants cancelled claims 11, 13, 14, 17 and 18. Claim 19 has been withdrawn as being drawn to a non-elected invention. Therefore, claims 1-10, 12, 15, 16 and 20-22 are the subject of this Office Action.

B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Claim Objections***

A. All claim objections have been withdrawn in view of Applicants' amendments to the claims.

### ***3. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. Claims 1-10, 12, 15, 16 and 20-22 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 5/13/02. Applicants argue that the disclosure of estrogen, a vector encoding SR-BI and an anti-SR-BI antibody provide broad support for a genus claim. However, though these three means of altering fertility are encompassed by the desired genus, they, alone, do not provide adequate written description for the entire genus of compounds able to alter fertility. In addition, Applicants, respectfully, have argued numerous times that estrogen is not encompassed by the claimed invention. Regardless, it would be expected that a nucleic acid encoding the target receptor, or an antibody against the target receptor would have the desired effects. Though these compounds have been shown to alter cholesterol levels in a mammal, they have not been shown to alter fertility. Again, Applicants are claiming a universe of compounds which alter fertility while only demonstrating a few means of altering cholesterol levels in a mammal, including estrogen (Example 3 on pages 39-40 of the specification), adenoviral vector encoding SR-BI (Example 5 on pages 40-45 of the specification), and anti-SR-BI antibody (Example 8 on pages 55-66 of the specification). Applicants have not demonstrated any other compounds which alter cholesterol levels, or fertility, in a mammal.

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Applicants argue that they have disclosed an extensive list of molecules on page 11 of the specification which inhibit SR-BI. However, this list includes molecules which bind SR-BI and compounds which block binding of HDL to SR-BI. It is these groups of compounds which lack the greatest written description. Applicants have only identified estrogen as belonging to one of these classes. Based on this, Applicants are claiming methods using any molecules which bind SR-BI and compounds which block binding of HDL to SR-BI. Though Applicants are claiming methods, and not the compounds themselves, Applicants still have not provided any written description of these compounds, or any effective amounts to treat reproductive disorders in a mammal, nor have Applicants shown that any of these compounds, or antibodies, or nucleic acids, are effective in this treatment. Again, Applicants have only described that knocking out the SR-BI gene produces sterile (i.e. altered fertility) transgenic female mice (Example 6, pages 45-54 of the specification). Applicant has only demonstrated that completely knocking out the SR-BI gene (i.e. from all tissues) causes female mice to be infertile (Example 6). However, in the other examples in the specification, Applicant does not describe how altering SR-BI levels in these tissues alone affects fertility or reproductive disorders in a mammal, or if altering SR-BI levels *at all* in these tissues is sufficient to alter fertility or treat *any and all* reproductive disorders in a mammal. Therefore, though Applicants have taught a method of screening for compounds which alter fertility, as well as a method of drug design, these are general concepts, as no compounds have been described which can be used in the claimed invention. The teachings of Miettinen et al. have been considered and, though a link between cholesterol and fertility may have been established, the present specification still does not adequately describe compounds which perform the claimed function. Finally, though Applicants argue that the claims do not read on treating "any and all" reproductive disorders, the limitation in the claims of "treating a reproductive disorder" does appear to encompass any and all reproductive diseases. It is, respectfully, not understood how this limitation could be otherwise interpreted.

#### **4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement**

A. Claims 1-10, 12, 15, 16 and 20-22 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-9 of the Office Action dated 5/13/02. Applicants have not addressed these arguments. Therefore, the arguments of the previous Office Action are maintained, as well as for any reasons in the above rejection under 35 USC 112, first paragraph, which are pertinent to this rejection.

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**5. Claim Rejections - 35 USC § 112, second paragraph**

A. Claims 1-10, 12, 15, 16 and 20-22 remain rejected for the reasons already of record on page 9 of the Office Action dated 5/13/02. Applicants argue that the claims are not incomplete and that the only step that is required for treatment is defined by the claims. Applicants have amended the claims to recite that an effective dosage must be administered and that the mammal must be in need of treatment. While these limitations do help, they are lacking a conclusion step, or some measurement of an endpoint, for example, "wherein the ability of an animal to give birth means that fertility has been altered." **No new matter should be added.**

B. The rejection of claims 2 and 4-7 has been withdrawn. Applicants amended claims 4-7 to recite "a tissue." However, the issue was with the lack of antecedent basis for the term "the tissue" in claim 2. Claims 4-7 were rejected since they depend from claim 2. However, upon further consideration, the term "the tissue" in claim 2 does not lack antecedent basis since the term "tissue" does not need to be recited in claim 1 in order to provide basis for claim 2. Applicants, if they desire, can amend claims 4-7 to recite "the tissue" as previously written. The Examiner apologizes for this misunderstanding.

**6. Double Patenting**

A. The rejection of claims 1-10, 12, 15, 16 and 20-22 as being obvious over claim 1-10 of US Patent No. 5,962,322 has been withdrawn in view of Applicants arguments and amendments to the claims limiting the population to females in need of treatment for a reproductive disorder.

**7. Claim Rejections - 35 USC § 102**

A. All rejections under 35 USC 102 have been withdrawn in view of Applicants' arguments and amendments to the claims to recite that the method is to be practiced on a female patient in need of treatment of a reproductive disorder.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Advisory information***

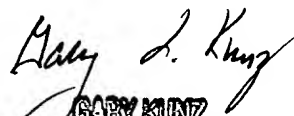
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
February 04, 2003

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**